identified four products: trastuzumab emtansine, sofosbuvir, dolutegravir and riociguat. All had been assessed by CEESP and SMC; only one NICE assessment was published (sofosbuvir). For all products, except sofosbuvir, the type of model was different between agencies. All the published CEESP opinions reviewed cost-effectiveness (CEA) and cost-utility analyses (CUA) whereas SMC and NICE only published CUA. Comparators and perspectives used were also different. For trastuzumab emtansine, the Incremental Cost Effectiveness Ratio (ICER) published by SMC was 26.5% lower than the one published by CEESP. According to SMC guidance, riociguat and dolutegravir were dominant versus comparators, whereas CEESP published ICERs of 108 876 €/QALY and 16 526 €/QALY respectively. For sofosbuvir, most UK ICERs were higher than French ones. **CONCLUSIONS:** Results confirm differences in recommendations and methodological requirements between the three agencies. Comparator heterogeneity due to different local practices appears to be a key factor leading to discrepancies in ICERs and cost-effectiveness assessment. ICERs were higher in France than in the UK, possibly due to absence of established thresholds and no explicit impact on reimbursement decision.

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THE USE OF MOBILE HEALTH TECHNOLOGY IN PROMOTING INFANT VACCINE ADHERENCE – A HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: Persistently stubborn infant mortality rates across the world have prompted the use of mobile technologies to assist in vaccine adherence. This systematic review attempts to assess the efficacy of a mobile phone technology in delivering timely infant immunization reminders and ensuring compliance and follow-up rates. **METHODS:** Studies were identified based on pre-specified criteria from two journals (BMJ and Lancet) and three databases (PUBMED, Google Scholar and Cochrane). The articles were screened for PICO (Population, Intervention, Control and Outcome) parameters and subsequently shortlisted when they included the desired target population, namely infants and mothers and used the methodology of Randomized Controlled Trials (RCTs). Biases on account of dropouts, selection and blinding methods were taken into consideration. Risk ratios were analyzed for the review using a forest plot and bias graphs. **RESULTS:** A total of 71 studies were identified based on results of which 3 duplicates were excluded. Of the 68, 25 were screened for PICO parameters and eventually of the 22 full-text articles reviewed. 6 were RCTs and qualified as relevant for the Health Technology Assessment. The studies, published between 1996 and 2014, recorded the participation of 5999 infants and mothers across 5 clinic based interventions and 1 province-based intervention. A risk ratio of 0.67 indicates that the mobile-based intervention is 45% more effective than the control, suggesting the former to be a crucial measure to improve outcome measures such as timeliness of immunization and increased infant vaccine awareness. **CONCLUSIONS:** Our analysis suggests that the use of mobile technologies could marginally improve compliance in the intervention groups, even if they do not affect the overall immunization rates. The evidence also shows that incorporating this scheme into an existing health system requires a small investment that could potentially result in sizeable gains in reducing infant and neonatal mortality and morbidity, particularly in resource-limited settings.

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VARIABILITY IN CLINICAL COMPARATORS AND STANDARDS OF CARE: CONSEQUENCES FOR PAN-EUROPEAN RELATIVE EFFICACY

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OBJECTIVES: There has been significant discussion on implementing a single Health Technology Assessment (HTA) process in Europe, in part because of the high level of variability among existing agencies. Agencies often disagree on the reimbursement decisions and on the economic and clinical conclusions. While disagreement on economic evaluations and reimbursement decisions can be explained by different agency remits and healthcare budgets, the driving factors of and justifications for clinical variability are currently unknown. This analysis examines drivers of clinical variability, specifically the clinical comparator, and uses case studies to explore instances where different comparators were used. **METHODS:** 198 reviews from NICE, SMC, PBAC, HAS and CADTH's Common Drug Review were analyzed. Therapeutics were matched on indication, and the most recent review since 2007 for each agency was included if it was also reviewed by NICE. Agreement with NICE on the clinical comparator(s) used and on clinical evaluations were evaluated. **RESULTS:** Agreement with NICE on the clinical comparator(s) ranged from 40% to 65%. Other agencies agreed with NICE's clinical evaluations slightly more often when they also agreed on the comparator (54% vs. 45%); however, this trend was not statistically significant (p=.31). Case study evaluations indicated that differences in country standards of care and agencies' willingness to accept comparators used in the clinical trials were common concerns in cases of comparator disagreement. **CONCLUSIONS:** While there appears to be variability between NICE and the other agencies in comparator(s) evaluated, this does not appear to be a driving factor in clinical variability. Where differences in comparator(s) exist, a main theme identified was the differences in standards of care between countries. If agencies evaluate different comparators because of local standards of care, different agencies would have to be willing to accept comparators not in line with their standard practices in order to implement a pan-European system.

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DOES CONDITIONAL MARKETING AUTHORISATION INFLUENCE MARKET ACCESS IN FRANCE, ENGLAND, AND GERMANY?

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OBJECTIVES: In 2006, Conditional Marketing Authorisation (MA) was implemented by the European Medicines Agency (EMA) to ensure early access to innovative medications for patients in Europe. The objective of this study is to compare the health technology assessment (HTA) process in France, England, and Germany for medicines having received a conditional approval over the past 9 years **METHODS:** The present study concerned all medicines having been approved with a conditional MA. The HTA assessments performed by three national bodies, IQWiG, NICE and HAS, were compared for these products. **RESULTS:** Of the 19 medicines for which a conditional MA was requested, 17 have received an approval of this type. Three of these approved medicines have not yet been assessed by any of the three HTA bodies, or are currently undergoing assessment. Four medicines have undergone HTA assessment by all three agencies. An additional 9 medicines have been assessed in two of the three countries (4 by both HAS and NICE and 5 by both HAS and IQWiG). Whereas all products assessed by HAS received a favourable opinion for reimbursement, NICE and IQWiG are more restrictive in their recommendations. Indeed, only 1/8 medicines assessed by NICE received a favourable recommendation and 5/ 9 by IQWiG. Of note, a specific regulatory framework has been implemented in Germany by which IQWiG considers all orphan products approved by EMA to provide an added medical benefit. This disposition concerned 4 of the 5 products having received a favourable opinion in Germany. **CONCLUSIONS:** The HTA assessments by HAS, IQWiG and NICE of medicines having received a conditional approval are heterogeneous and lead to differing reimbursement statuses. Different criteria are taken into consideration, including the relevance of the comparator, the clinical trial design and endpoints as well as the relevant target population and health economic assessment.

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IMPLEMENTING THE FULL ECONOMIC EVALUATIONS OF MEDICINES IN THE HTA PROGRAMMES IN CATALONIA: FIRST STEPS AND FUTURE PERSPECTIVES

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OBJECTIVES: In 2014 the Catalan Health Service (CatSalut) published a guide (GAEIP) which describes the methodology for the economic evaluation of medicines in Catalonia. Now the objective is to design the operational aspects to introduce both the economic evaluations (EE) and budget impact analyses (BIA) of medicines in the three Health Technology Assessment (HTA) programmes of CatSalut. **METHODS:** The Commission for Economic Evaluation and Budget Impact (CAEIP) of CatSalut led the project that: 1) reviewed the processes undertaken by other countries that use EE/BIA of medicines; 2) ran focus groups with representatives of each of the three HTA programmes: primary and community care (PHF-APC), hospital medicines administered in ambulatory care (PHF-MHDA), and orphan medicines (PASFTAC); 3) validated the proposal through pilots in each programme. **RESULTS:** The project delivered a general framework to implement the EE and BIA in the current processes of each of the three HTA programmes, allowing them to fit it into their timings and particular needs. According to this proposal, companies will submit their EE and BIAs of medicines in a similar way to what they currently do in single technology appraisals. The HTA programmes will assess the quality of the submitted information, and may ask for additional analyses when required. To date, the pilot on the therapeutic area of oncology has been completed (PHF-MHDA) whilst the other two are still ongoing. CAEIP also developed a set of formularies to be used by the companies when submitting the required information. Finally, the project was informative, as it highlighted the size the resources needed to implement this new process within the HTA programmes. **CONCLUSIONS:** CatSalut continues with the deployment of EE and BIA as it believes both to be valuable when issuing recommendations on the use and the therapeutic positioning of medicines within the Catalan health system.

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ANALYSIS OF FOUR EARLY DIALOGUES (ED) AS PART OF THE SEED (SHAPING EUROPEAN EARLY DIALOGUES) PILOT: LESSONS LEARNT AND WAY FORWARD. SANOFI'S PERSPECTIVE

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OBJECTIVES: ED processes between manufacturers, Regulators and HTAs was developed to improve quality of evidence and patient access to new medicines. SEED is a pilot project financed by the EC involving 14 EU HTAs. Sanofi engaged in HTA ED with or without Regulators in four different occasions. This is an overview of lessons learnt and suggestions for future improvements. **METHODS:** In order to collect quantitative and qualitative information on the execution of the pilots and to evaluate their impact on evidence generation, Sanofi conducted a cross sectional analysis amongst all departments involved in the four EDs through: - An ad hoc questionnaire probing quality of process, feedback and consensus across agencies - Candid meetings to refine response interpretation. **RESULTS:** Approval requests, Briefing Book (BB) completions and clarifications were straightforward, although coordination was sometimes lacking. Process timelines seemed appropriate, nevertheless great variability in Sanofi's efforts was observed depending on the therapeutic area and the type of advice sought. Teams were generally satisfied with the meetings, with good contributions from stakeholders and topics properly addressed. However, relevant items not reported in the BB could not be raised during the discussion, not all attendees were involved in national negotiations and patients were not consistently represented. The quality of the feedback before, during and after the meeting was satisfactory. Yet, seeking consensus across HTAs was not observed, nor the final report always consistent with meeting discussions. **CONCLUSIONS:** Sanofi satisfaction about the ED experience was generally high, allowing to pressure test evidence development plans and scenarios, while garnering feedback on critical items from multiple countries. In order to truly improve evidence generation, some flexibility during the meeting should be allowed and consensus of opinion/advice achieved. All teams agreed on consulting in similar EDs in the future.